IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

Brewer et al.

Div. of Appln. No.: 09/469,954

Filed: January 4, 2002

Title: DETERMINATION OF MASK FITTING PRESSURE AND CORRECT MASK FIT

Confirmation No.: Unknown

Group Art Unit: 3761

Examiner: M. Patel

January 4, 2002

* * * * *

PRELIMINARY AMENDMENT

Hon. Commissioner of Patents
Washington, D.C. 20231

Sir:

Before examination on the merits, please amend the above-identified application as follows:

IN THE SPECIFICATION:

Page 1, line 1, please insert the following new paragraph

--CROSS REFERENCE TO RELATED APPLICATION

This application is a Divisional of U.S. Application No. 09/469,954, filed December 21, 1999, the specification of which is incorporated by reference for all purposes.—

Please replace the paragraph appearing on page 7, lines 4-9 as follows:

During the Mask-Fit mode, the microcontroller 38 continuously determines mask leak as the value, f_{LEAK}, as described above, comparing this to a threshold, typically of 0.2 l/s, and providing the patient with a visual indication 44 of degree of leak. This threshold represents

the 'no leak' degree. In this way the patient can manipulate the mask to ensure correct fitting as indicated by the appropriate message.

See the attached Appendix for the changes made to effect the above paragraph

IN THE CLAIMS:

Please cancel claim 1 without prejudice.

Please add the following new claim(s):

27. A method for determining a mask-fit test pressure to be applied to a wearer's mask by ventilaltory assistance apparatus, wherein the mask-fit pressure is adaptively determined from prior use.

28. In a continuous positive airway pressure apparatus having an automatic titration mode that delivers a flow of pressurized breathable gas to a patient mask, a method for determining of a mask-fit pressure to be applied to a wearer's mask by the apparatus, said method comprising:

measuring by a pressure sensor the mask pressure used by a patient during a treatment session; and

determining a mask fit test pressure from the pressures used by the patient during the treatment session.

29. A method for determining a mask-fit test pressure to be applied to a wearer's mask by ventilatory assistance apparatus, the method comprising:

determining a percentile pressure of a previous ventilatory assistance session to be said test pressure.

30. The method of claim 29, wherein said percentile pressure is chosen from the range of the 75^{th}-95^{th} percentile pressure.

31. The method of claim 30 further comprising determining a base pressure to be said test pressure if there is no previous pecentile pressure available.

32. The method of claim 31, wherein said base pressure is in the range of 10-12 cm H_2O.

33. The method of claim 32, further comprising determining that a previous pressure is available if a pressure ventilatory assistance session occured for greater than a predetermined time interval.

34. The method of claim 33, wherein said predetermined time interval is three hours.

35. A method for assessing correct fitting of a mask delivering ventilatory assistance, provided by ventilatory assistance apparatus, to a wearer of the mask, the method comprising:

determining a percentile pressure of a previous ventilatory assistance session to be applied as a test pressure;

determining leak flow from said mask at the test pressure; and

displaying or otherwise indicating a magnitude of the leak flow as an indication of correct mask fitting.

36. The method of claim 35, wherein said leak flow is quantized to represent a degree of leak.

37. The method of claim 36, further comprising:

comparing said leak flow against a threshold value representing zero degree of leak; and

determining that there is correct mask fitting if the threshold is not exceeded.

38. The method of claim 36, further comprising determining a base pressure to be applied as said test pressure if there is no previous percentile pressure available.

39. The method of claim 38, wherein said percentile pressure is chosen from the range of the 75th-95th percentile pressure.

40. The method of claim 39, wherein said base pressure is in the range of 10-12 cm H_2O.

41. The method of claim 39, further comprising determining that a previous pressure is available if a pressure ventilatory assistance session occured for greater than a predetermined time interval.

42. The method of claim 41, wherein said predetermined time interval is three hours.

43. A method for determining a mask-fit positive test pressure to be applied to a wearer's mask by ventilatory assistance apparatus, the method comprising:

determining a percentile pressure of a previous ventilatory assistance session to be said positive test pressure.

44. The method of claim 43, wherein said percentile pressure is chosen from the range of the 75th-95th percentile pressure.

45. The method of claim 43 comprising determining a base pressure to be said positive test pressure if there is no previous pecentile pressure available.

46. The method of claim 45, wherein said base pressure is in the range of 10-12 cm H_2O.

47. The method of claim 43, further comprising determining that a previous pressure is available if a pressure ventilatory assistance session occured for greater than a predetermined time interval.

48. The method of claim 47, wherein said predetermined time interval is three hours.

49. A method for assessing correct fitting of a mask delivering ventilatory assistance, provided by ventilatory assistance apparatus, to a wearer of the mask, the method comprising:

determining a percentile pressure of a previous ventilatory assistance session to be applied as a positive test pressure;

determining leak flow from said mask at the positive test pressure; and

displaying or otherwise indicating a magnitude of the leak flow as an indication of correct mask fitting.

50. The method of claim 49, wherein said leak flow is quantized to represent a degree of leak.

51. The method of claim 49, further comprising:

comparing said leak flow against a threshold value representing zero degree of leak; and

determining that there is correct mask fitting if the threshold is not exceeded.

52. The method of claim 49, further comprising determining a base pressure to be applied as said positive test pressure if there is no previous percentile pressure available.

53. The method of claim 52, wherein said percentile pressure is chosen from the range of the 75^{th}-95^{th} percentile pressure.

54. The method of claim 52, wherein said base pressure is in the range of 10-12 cm H_2O.

55. The method of claim 49, further comprising determining that a previous pressure is available if a pressure ventilatory assistance session occured for greater than a predetermined time interval.

56. The method of claim 55, wherein said predetermined time interval is three hours.

IN THE ABSTRACT:

Please delete the present Abstract of the Disclosure and replace it with the new Abstract of the Disclosure provided on the attached separate sheet.

A CPAP treatment apparatus, as one form of positive pressure ventilatory assistance, includes a turbine/blower, operated by a mechanically coupled electrical motor that receives air or breathable gas at an inlet thereof, and supplies the breathable gas at a delivery pressure to a delivery tube/hose having a connection at the other end thereof with a nose mask. A microcontroller has an operational "Mask-Fit" mode. An initial constant pressure level is applied by the blower to the mask. If the functional mode is a manual mode, then the mask-fit test pressure is the current 'set' pressure. If the functional mode is the automatic titration mode, the mask-fit test pressure is the 95th percentile pressure of the previous session, otherwise it is the base treatment pressure, e.g. 10-12 cm H_2O. This constant pressure is applied for a period of time, typically 1-3 minutes. The microcontroller continuously determines mask leak as the value, f_{LEAK}, from a flow sensor, comparing this to a threshold, and providing the patent with a visual indication of degree of leak. In this way the patient can manipulate the mask to ensure correct fitting as indicated by the appropriate message or indication.

See the attached Appendix for the changes made to effect the above Abstract.

REMARKS

By this Preliminary Amendment, the specification has been amended, the abstract has been replaced, claim 1 has been cancelled and new claims 27-56 have been added. Applicants request that the examiner grant a personal interview to discuss the pending claims.

New claims 27 and 28 are supported by the original specification. See, e.g., page 3, lines 2-3. New claims 29-42 correspond to claims 1-14 of the parent application, which were rejected under 35 U.S.C. §§102(b), 103(a) over U.S. Patent No. 4,846,166 to Willeke (hereinafter "*Willeke*"). This rejection, as it may apply to claims 29-42, is respectfully traversed.

Claims 29 and 35 recite a method including determining a percentile pressure of a previous ventilatory assistance session to be said test pressure (claim 29) or to be applied as a test pressure (claim 35). *Willeke* does not teach the subject matter. *Willeke* states that the initial test pressure P_1 should be larger than 1 cm H_2Oat time t_1, preferably between 5 and 10 cm H_2O. Col. 10, line 67- Col. 11, line 1. Applicants respectfully submit that the "initial" pressure appears to correspond to a pressure which the wearer or worker creates during inhaling. Thus, the initial pressure is not based on a previous ventilatory assistance session, as claimed. Moreover, *Willeke* does not teach or suggest a method for determining a mask-fit positive test pressure as set forth in new claims 43-56.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached Appendix is captioned **"Version with markings to show changes made"**.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in a condition for allowance and a Notice to that effect is earnestly solicited.

Respectfully submitted,

Pillsbury Winthrop LLP

By: _____

Paul T. Bowen
Reg. No.:38009
Tel. No.: (703) 905-2020
Fax No.: (703) 905-2500

1600 Tysons Boulevard
McLean, VA 22102
(703) 905-2000
Enclosure: Appendix

APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The specification is changed as follows:

Page 1, line 1, please insert the following new paragraph

--CROSS REFERENCE TO RELATED APPLICATION

This application is a Divisional of U.S. Application No. 09/469,954, filed December 21, 1999, the specification of which is incorporated by reference for all purposes.--

Please replace the paragraph appearing on page 7, lines 4-9 as follows:

During the Mask-Fit mode, the microcontroller 38 continuously determines mask leak as the value, f_{LEAK}, as described above, comparing this to a threshold, typically of 0.2 l/s, and providing the patient with a visual indication 44 of degree of leak. This threshold represents the 'no leak' degree. In this way the patient can manipulate the mask to ensure correct fitting as indicated by the appropriate message.

IN THE CLAIMS:

Claim 1 is cancelled. New claims 27-56 are added.

IN THE ABSTRACT OF THE DISCLOSURE:

The abstract is changed as follows:

ABSTRACT OF THE DISCLOSURE

A CPAP treatment apparatus **[(10)]**, as one form of positive pressure ventilatory assistance, **[is disclosed. A]** includes a turbine/blower **[(14)]**, operated by a mechanically coupled electrical motor, **[(16) that]** receives air or breathable gas at an inlet **[(18)]** thereof, and supplies the breathable gas at a delivery pressure to a delivery tube/hose **[(20]** having a connection at the other end thereof with a nose mask **[(12)]**. A microcontroller **[(38)]** has an operational "Mask-Fit" mode. An initial constant pressure level is applied by the blower **[(14)]** to the mask **[(12)]**. If the functional mode is a **[Manual]** manual mode, then the mask-fit test pressure is the current 'set' pressure. If the functional mode is the automatic titration mode, the mask-fit test pressure is the 95th percentile pressure of the previous session, otherwise it is the base treatment pressure, e.g. 10-12 cm H_2O. This constant pressure is applied for a period of time, typically 1-3 minutes. The microcontroller **[(38)]** continuously determines mask leak as the value, f_{LEAK}, from a flow sensor **[(32)]**, comparing this to a threshold, and providing the patent with a visual indication of degree of leak. In this way the patient can manipulate the mask to ensure correct fitting as indicated by the appropriate message or indication.

ABSTRACT OF THE DISCLOSURE

A CPAP treatment apparatus, as one form of positive pressure ventilatory assistance, includes a turbine/blower, operated by a mechanically coupled electrical motor that receives air or breathable gas at an inlet thereof, and supplies the breathable gas at a delivery pressure to a delivery tube/hose having a connection at the other end thereof with a nose mask. A microcontroller has an operational "Mask-Fit" mode. An initial constant pressure level is applied by the blower to the mask. If the functional mode is a manual mode, then the mask-fit test pressure is the current 'set' pressure. If the functional mode is the automatic titration mode, the mask-fit test pressure is the 95th percentile pressure of the previous session, otherwise it is the base treatment pressure, e.g. 10-12 cm H_2O. This constant pressure is applied for a period of time, typically 1-3 minutes. The microcontroller continuously determines mask leak as the value, f_{LEAK}, from a flow sensor, comparing this to a threshold, and providing the patent with a visual indication of degree of leak. In this way the patient can manipulate the mask to ensure correct fitting as indicated by the appropriate message or indication.